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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MAYES, LAURIE A	

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,403	MEHUL ET AL.	
	Examiner	Art Unit	
	Laurie Mayes	1653	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *21-24 and 29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,25, 27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-32 are pending. Claims 1-20, 27 and 28 are rejected. Claims 21-26 and 29-32 are withdrawn from consideration as drawn to a non-elected group of invention.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-20 and 25 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the inventions share unity of invention. However, a mixture of polypeptides obtained from the proteolysis, Group I, claim 9, of SEQ ID NO: 1 would be anticipated (Hillman et al., US 6,046,315).

Hillman et al. teach a sequence with 99.6% sequence similarity to SEQ ID NO: 1 and fragments thereof (col. 2, lines 5-10) which would have anticipated claim 9. One skilled in the art at the time of the invention could use Kex 1 and Kex2 for proteolysis of the Hillman et al. sequence, which would cleave the peptide at the "KK" and "RK" positions, resulting in a mixture of polypeptides that would be the same as a "mixture of polypeptides obtained from the proteolysis of the polypeptide" of SEQ ID NO: 1 (present claim 9). Thus, the invention in claim 9 demonstrates lack of unity in that the special technical feature was known in the art. The restriction requirement is made FINAL.

As the applicant has elected Group I, drawn to a protein and the first method of use, namely, administering the protein in a therapeutically effective amount, claims 1-20, 25, 27 and 28 will be examined as Group I claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-15 are missing an article at the beginning of the claims; for example, claim 1 should be amended to read: "**A** purified natural . . .".

In claim 4, the language "purified from human skin" is indefinite as the source of the skin is unclear. The applicant may clarify this by amending the language to read "from cultured human skin", for example.

The language "in part comprises" in claim 6 is indefinite as being redundant. The term "comprises" already reads on a sequence having all the amino acids of SEQ ID NO:1 and with or without any additional amino acids.

In claims 7 and 8, the language "theoretical isoelectric point" and "theoretical molecular weight" is indefinite. How does these theoretical values differ from actual values?

Claims 10-14, 17, 18 and 25 are indefinite as the language "at least one" is unclear since there is only one peptide in claim 1.

Claim 11 is indefinite as it is unclear to what the calcium fixes.

The language "transglutaminases" in claims 17 and 18 is indefinite as it is unclear which transglutaminases? Transglutaminases in the epithelium? Do they show regulation of any transglutaminases and is location important? Also, the language "to a patient in need of such regulation" is indefinite as it is unclear how one would diagnose this need.

Claims 16 and 20 are indefinite as the term "neoplasias" is unclear. Does the method treat sarcoma, for example?

In claim 12, the language "effective amount" is indefinite as it is unclear what the effective amount is for. Dependent claim 19 is rejected as it depends on indefinite claim 12. In claim 13, the language "intended to regulate the impairments of epidermal, normal or pathological proliferation or differentiation, comprising . ." is indefinite because the term "epidermal" is an adjective. Is it intended to regulate impairments of the epidermal layer of skin or the epidermis? Also, "normal or pathological proliferation or differentiation" of what?

The applicant is reminded that the intended use of a composition, as listed in claim 13, has no patentable weight in composition claims.

Objections to Specification

The use of the trademarks COMPLETE (spec. p. 29) and MULTIPHOR (p. 27) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification, p. 25, is objected to as it contains primer sequences more than four amino acids in length and fail to recite "SEQ ID NO: ___". See 37 CFR 1.821-1.825.

Objections to Claims

Claim 10 is objected to as containing an additional "in" (see "wherein in" in line 1) and as it contains a misspelling of the word "one" (line 2).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention in claim 6 as directed to a "natural . . . polypeptide whose sequence in part comprises the sequence of the polypeptide as described in claim 1" is found naturally occurring in nature in the skin of animals.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Flavell et al. (US 5,747,294). Flavell et al. teach a recombinant protein that is obtained by expression of an expression vector pGex-2T that contains part of the sequence (for example, ATG) that codes SEQ ID NO: 2 (col. 27, lines 33-45 and Fig. 1a: Met/ ATG). Thus, all of the elements of claim 28 are anticipated by Flavell et al.

Claims 6 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al. (US 6,046,315). Hillman et al. teach a recombinant DACP-1 which has an amino acid sequence with 99.6% identity to SEQ ID NO: 1 (see sequence listing cols. 35 and 36). Thus, Hillman et al. teach a recombinant protein that corresponds to part of SEQ ID NO: 1 (present claims 6 and 27). Further, the protein taught by Hillman et al. has an amino acid sequence with 99.6% identity to SEQ ID NO: 1 with an arginine at position 64 in place of a lysine. Thus, all of the elements of claims 6 and 27 are taught by Hillman et al. and these claims are anticipated under 35 U.S.C. 102(e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. Hillman et al. teach a sequence with 99.6% sequence similarity to SEQ ID NO: 1 and fragments thereof (col. 2, lines 5-10) which are useful in treating disorders. It would have been obvious to one of ordinary skill in the art at the time of the invention to use Kex 1 and Kex2 for proteolysis of the Hillman et al. sequence into fragments, which would cleave the peptide at the "KK" and "RK" positions, resulting in a mixture of polypeptides that could be the same as a "mixture of polypeptides obtained from the proteolysis of the polypeptide" of SEQ ID NO: 1 (present claim 9).

Conclusion

Claims 1-20, 27 and 28 are rejected. The full length polypeptide of SEQ ID NO: 1 and methods of its use appear free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
May 30, 2003

Christopher S. F. Low

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